



Euromi Sa
Curtis Raymond
Sr Regulatory & Quality Consultant
80 Shelton Technology Center
Shelton, Connecticut 06484

June 9, 2021

Re: K101413
Trade/Device Name: Euromi Eva Sp6
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Curtis Raymond:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 16, 2010. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

DEC 16 2010

Euromi SA
% Orchid Design
Mr. Curtis Raymond
80 Shelton Technology Center
Shelton, Connecticut 06484

Re: K101413

Trade/Device Name: Euromi EVA sp6 Lipoplasty Suction System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MUU
Dated: October 18, 2010
Received: October 20, 2010

Dear Mr. Raymond:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

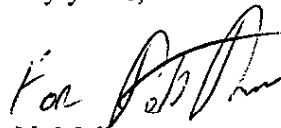
Page 2 - Mr. Curtis Raymond

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Euromi EVA sp6 Lipoplasty Suction System

Indications For Use:

The device is intended to be used for aesthetic body contouring.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Daniel Kruse for MxM
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101413

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510 (k) Summary

Date Prepared: [21 CFR 807.92(a)(1)]
December 1, 2010

DEC 16 2010

Submitter's Information: [21 CFR 807.92(a)(1)]

This 510(k) is being submitted by Orchid Design on behalf of Euromi SA.

Sponsor / Manufacturer:

Euromi S.A.
Zoning Industriel de Lambermont
Rue des Ormes 151
B-4800 Verviers - BELGIUM

Regulatory Contact / Consultant:

Curtis Raymond
Orchid Design
80 Shelton Technology Center - Shelton, CT 06484
Tel: (203) 922-0105 - Fax: (203) 922-0130
Email: joseph.azary@orchid-orthopedics.com

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Device Trade or Proprietary Name:

The device trade names are:

- Euromi EVA sp6 Lipoplasty Suction System

Common, Usual, or Classification Name:

- Lipoplasty Suction System
- Liposuction Suction System

Classification: Class II, 21 CFR 878.5040, MUU

Predicate Device [21 CFR 807.92(a)(3)]

Byron Medical, PSI-Tec Liposuction, K981215
Byron Medical, PSI-Tec Infiltration Pump, K040149

Description of the Device [21 CFR 807.92(a)(4)]

The subject device is used in conjunction with the Lipomatic Handpiece. The Lipomatic Handpiece is a motorized pneumatic handle with interchangeable canulae. The Lipomatic handpiece can be used with readily available air sources at the hospital or clinic.

The EVA sp6 is an aspiration system that can be used with the Lipomatic handpiece for the purposes of aesthetic body contouring.

The EVA sp6 can be in continuous operation or can be controlled by a foot pedal. The device has two modes; infiltration and aspiration. Syringes are used for infiltration.

The EVA sp6 has wheels to allow it to move around the clinical or hospital as needed.

The list of accessories include:

- Pedal
- Hospital Grade Power Cord and Plug
- Replacement Fuses
- Tubing (5 kits)
- Twisted Pipe of 5 meter with one connector
- Aspiration Jars (2 jars)

Intended Use [21 CFR 807.92(a)(5)]

This device is intended to be used for aesthetic body contouring.

Technological Characteristics [21 CFR 807.92(a)(6)]

The device relies on an external source of compressed air for operation.

The EVA sp6 does not make direct contact with the patient. The device is connected to the Lipomatic Handpieces / Cannulas that were cleared under K010311.

The device has the same technological characteristics as the predicate device including electrical power, use with sterile cannulas, indications for use, and aspiration and infiltration modes.

The main difference between the subject device and predicate device is that the devices are specific to the cannulas from each manufacturer.

Performance Data [21 CFR 807.92(b)(1) and (2)]

The subject device has been subjected to non-clinical testing including biocompatibility testing, electrical safety, EMC testing, FCC Part 15, and accuracy testing. The subject device has been tested and passed electrical safety and EMC requirements utilizing IEC 60601-1, 60601-1-2, and FCC Part 15.

Characteristic	Specification
Electrical	110-120 V
Power	250 W
Noise Level	57 dB
Weight	10 Kg
Final Vacuum (mb relative)	-850

Clinical studies were not performed with regards to this device. However, this device has been used internationally and published studies were included in the 510(k).

Clinical data was not required to demonstrate substantial equivalence.

Conclusion [21 CFR 807.92(b)(3)]

The conclusions drawn from the nonclinical tests as well as the comparison to the predicate device demonstrate that the changes are minor and conclude that the subject devices are as safe and effective as the predicate device.